

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 2 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1.-45. (Cancelled)

46. (Currently Amended) A pharmaceutical aerosol formulation comprising a hydrofluoroalkane (HFA) propellant; a physiologically effective amount of a medicament for inhalation; and an alkyl saccharide surfactant, wherein the medicament is in particle form.

47.-53. (Cancelled)

54. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the surfactant is selected from the group consisting of an alkyl glucoside and an alkyl maltoside.

55. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 54, wherein the surfactant is selected from the group consisting of decyl glucoside and dodecyl maltoside.

56. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the formulation comprises a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227), or 1,1-difluoroethane (P152a).

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 3 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

57. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 56, wherein the formulation comprises a propellant mixture comprising 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

58. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 57, wherein the formulation comprises a density-matched propellant mixture of 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

59. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the medicament is selected from the group consisting of a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, and a glucocorticosteroid.

60. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the medicament is selected from the group consisting of salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, mabuterol, ipratropium bromide, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and pharmacologically acceptable esters and salts thereof.

61. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the medicament is selected from the group consisting of anti-allergic medicaments, expectorants, mucolytics, antihistamines, cyclooxygenase inhibitors, leukotriene synthesis inhibitors, leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists, prophylactics of asthma, antiarrhythmic medicaments, tranquilisers,

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 4 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic medicaments, antiparasitic medicaments, anticancer medicaments, sedatives, analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapeutic agents, antifungal medicaments, antihypotension medicaments, vaccines, antiviral medicaments, proteins, peptides, vitamins, cell surface receptor blockers, antioxidants, free radical scavengers, and organic salts of N,N'-diacetylcystine.

62. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, including ethanol in an amount of up to 20% by weight of propellant and surfactant.

H
cont.
63. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, including ethanol in an amount of up to 5% by weight of propellant and surfactant.

64. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, further comprising a substance selected from the group consisting of adjuvants, carriers, flavouring agents, buffers, antioxidants and chemical stabilisers.

65. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein at least 50% of the medicament consists of particles having a diameter of 0.01-10 microns.

66. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein at least 50% of the medicament consists of particles having a diameter of 0.1-6 microns.

Applicant : Kjell Bäckström et al.
 Serial No. : 08/601,005
 Filed : March 1, 1996
 Page : 5 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

67. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein at least 50% of the medicament consists of particles having a diameter of 0.1-5 microns.

68. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 65, wherein at least 70% of the medicament consists of particles having a diameter of 0.01-10 microns.

69. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 65, wherein at least 90% of the medicament consists of particles having a diameter of 0.01-10 microns.

70. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 66, wherein at least 70% of the medicament consists of particles having a diameter of 0.01-6 microns.

71. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 66, wherein at least 90% of the medicament consists of particles having a diameter of 0.01-6 microns.

72. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the concentration of medicament in the formulation is 0.1 mg/ml to 25 mg/ml.

73. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the ratio of surfactant to medicament is in the range of 1:50 to 1:0.2.

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 6 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

74. (Previously Presented) A method for the manufacture of a pharmaceutical aerosol formulation as claimed in claim 46, comprising the steps of:

- mixing the medicament and the surfactant in a vessel;
- adding propellant to the vessel; and
- mixing the propellant with the medicament/surfactant mixture to produce a medicament/surfactant/propellant mixture.

H
CONT.
75. (Previously Presented) The method of claim 74, further comprising the step of mixing additional propellant with the medicament/surfactant/propellant mixture.

76. (Currently Amended) A method for the treatment of a patient in need of therapy with a medicament, comprising administering to said patient a therapeutically effective amount of a pharmaceutical aerosol formulation comprising a HFA propellant; a physiologically effective amount of the medicament; and an alkyl saccharide surfactant, wherein the medicament is in particle form.

77. (Previously Presented) The method of claim 76, wherein the formulation comprises a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227), and 1,1-difluoroethane (P152a).

78.-79. (Cancelled)

80. (Previously Presented) The method of claim 76, wherein the surfactant is selected from the group consisting of an alkyl glucoside and an alkyl maltoside.

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 7 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

81. (Previously Presented) The method of claim 76, wherein the medicament is selected from the group consisting of a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, and a glucocorticosteroid.

82. (Previously Presented) The method of claim 76, wherein the medicament is selected from the group consisting of anti-allergic medicaments, expectorants, mucolytics, antihistamines, cyclooxygenase inhibitors, leukotriene synthesis inhibitors, leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists, prophylactics of asthma, antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic medicaments, antiparasitic medicaments, anticancer medicaments, sedatives, analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapeutic agents, antifungal medicaments, antihypotension medicaments, vaccines, antiviral medicaments, proteins, peptides, vitamins, cell surface receptor blockers, antioxidants, free radical scavengers, and organic salts of N,N'-diacetylcystine.

83. (Previously Presented) The method of claim 76, wherein the ratio of surfactant to medicament is in the range of 1:50 to 1:0.2.

84. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of a β 2-adrenoreceptor agonist and a glucocorticosteroid.

85. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 84, further comprising a physiologically effective amount of an anticholinergic bronchodilator.

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 8 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

86. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) budesonide, or a salt, ester, solvate, or solvate of a salt or ester thereof.

87. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) mometasone, or a salt ester, solvate, or solvate of a salt or ester therefor.

H'
Cont.
88. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) fluticasone, or a salt, ester, solvate, or solvate of a salt or ester thereof.

89. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of (a) salmeterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) fluticasone, or a salt, ester, solvate, or solvate of a salt or ester thereof.

90. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of a β 2-adrenoreceptor agonist and a glucocorticosteroid.

91. (Previously Presented) The method of claim 90, wherein the formulation further comprises a physiologically effective amount of an anticholinergic bronchodilator.

92. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate,

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 9 f14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

or solvate of a salt or ester thereof; and (b) budesonide, or a salt, ester, solvate, or solvate of a salt or ester thereof.

93. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) mometasone, or a salt ester, solvate, or solvate of a salt or ester therefor.

94. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) formoterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) fluticasone, or a salt, ester, solvate, or solvate of a salt or ester thereof.

HI
Cont. 95. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) salmeterol, or a salt, ester, solvate, or solvate of a salt or ester thereof; and (b) fluticasone, or a salt, ester, solvate, or solvate of a salt or ester thereof.

96. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 46, wherein the surfactant is decyl glucoside.

97. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 46, wherein the surfactant is dodecyl maltoside.

98. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 56, wherein the surfactant is decyl glucoside.

99. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 56, wherein the surfactant is dodecyl maltoside.

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 10 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US

100. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 57, wherein the surfactant is decyl glucoside.

101. (Previously Presented) The pharmaceutical aerosol formulation as claimed in claim 57, wherein the surfactant is dodecyl maltoside.

102. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, the formulation comprising a physiologically effective amount of each of (a) formoterol and (b) budesonide.

103. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) formoterol and (b) budesonide.

104. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the formulation comprises a physiologically effective amount of each of (a) an anticholinergic bronchodilator and (b) a β 2-adrenoreceptor agonist.

105. (Previously Presented) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the formulation comprises a physiologically effective amount of each of (a) an anticholinergic bronchodilator and (b) a glucocorticosteroid.

106. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) an anticholinergic bronchodilator and (b) a β 2-adrenoreceptor agonist.

107. (Previously Presented) The method of claim 76, wherein the formulation comprises a physiologically effective amount of each of (a) an anticholinergic bronchodilator and (b) a glucocorticosteroid.

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Page : 11 of 14

Attorney's Docket No.: 06275-034001 / D 1371-1 US